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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ensoli Confirmation No.: 9400
Application No.: 09/555,534 Art Unit: 1648
Filed: May 31, 2000 Examiner: Stucker, Jeffrey J.
For: HIV TAT, OR DERIVATIVES Attorney Docket No.: 11340-003-999
THEREOF FOR PROPHYLACTIC (formerly 204.610)
AND THERAPEUTIC
VACCINATION

DECLARATION OF BARBARA ENSOLI, M.D., Ph.D. UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, BARBARA ENSOLI, M.D., Ph.D., do declare as follows:

1. I am the inventor of the above-identified patent application. My education and experience are summarized on my Curriculum Vitae, which is attached hereto as Exhibit 1.
2. I am a co-author of Chang *et al.*, 1997, AIDS 11:1421-1431 ("the Chang reference;" attached hereto as Exhibit 2).
3. I have been asked to consider what one of ordinary skill in the art would have understood about the first method for isolation of HIV-1 Tat protein described in the Chang reference. In particular, I have been asked to consider what one of skill in the art would have understood, as of the first claimed priority date of the present application, *i.e.*, December 1, 1997, from the Chang reference regarding (1) the order of the ion-exchange chromatography and the HPLC steps, and (2) what solvents may have been used in the reverse phase HPLC step.
4. The first purification method of the Chang reference is described on page 1424 under the heading "Tat protein and anti-Tat antibody." The Chang reference states that the procedure involves expression of the protein in *E. coli* and then isolation of Tat through

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successive rounds of high-pressure liquid chromatography (HPLC) and ion-exchange chromatography, which the Chang reference indicates is performed as described in two earlier references, i.e., reference 18, which is Ensoli *et al.*, 1993, *J. Virology* 67: 277-287 (attached as Exhibit 3), and reference 44, which is Bohan *et al.*, 1992, *Gene Expression* 2:391-407 (attached as Exhibit 4). The relevant passage of Ensoli *et al.*, reference 18, is on page 278, column 1. The relevant passage of Bohan *et al.*, reference 44, is in the paragraph spanning pages 393 to 395, which indicates that the Tat protein was purified by successive rounds of molecular sieve and HPLC reverse phase chromatography.

5. Although not explicitly stated in Ensoli *et al.* or Bohan *et al.*, it is my opinion that one skilled in the art would know that HPLC preferably is not performed on crude bacterial extracts (see, e.g., Chris Shaw, *Methods in Molecular Biology*, Vol. 32: *Basic Protein and Peptide Protocols*, Chapter 31, page 275, 6th sentence under Introduction, Edited by J.M. Walker, 1994, Humana Press Inc., hereinafter "Shaw", attached as Exhibit 5). The skilled artisan also would have been aware that a reverse-phase fractionation is generally unfeasible on crude extracts and is desirable after ion-exchange in order to facilitate removal of ion-exchange buffer salts (see, e.g., Shaw, at page 281, attached as Exhibit 5; and Jan-Chister Janson and Lars Rydén in *Protein Purification*, Chapter 1, pages 16-18, Edited by VCH Publishers Inc., 1989, attached as Exhibit 6). Thus, it is my opinion that one skilled in the art would have understood that in each successive round, the HPLC step would have been performed after the ion-exchange chromatography, and thus the eluted Tat protein would be tainted with HPLC buffer.

6. Although neither the Chang reference, nor Ensoli *et al.*, nor Bohan *et al.* indicate what solvent was used in the reverse phase HPLC, a solvent commonly used in reverse phase HPLC, as of the priority date of the above-identified application, was acetonitrile, particularly acetonitrile containing some amount of trifluoroacetic acid (TFA) (see, e.g., Shaw, at page 280, attached as Exhibit 5; Michael E. Byrnes, *Methods in Molecular Biology*, Vol. 32: *Basic Protein and Peptide Protocols*, Chapter 4, page 42, Edited by B.M. Dunn and M.W. Pennington, 1994, Humana Press Inc., attached as Exhibit 7; and Paul C. Sadek, *The HPLC Solvent Guide*, Chapter 7, Section 7.6.4 on page 251, 1996, John Wiley & Sons, Inc., attached as Exhibit 8). Indeed, a buffer containing acetonitrile and TFA was actually used in the reverse phase HPLC step of the Chang reference.

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7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that I make these statements with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and any patent issuing thereon.

Date: 12-13, 2005

Barbara Ensoli
Barbara Ensoli, M.D., Ph.D.

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CURRICULUM VITAE

Name: Dr. Barbara Ensoli

Date and Place of Birth: January 23, 1960; Latina, Italy

Education:

- 1978-1984 - University of Rome "La Sapienza", Medical School, Rome, Italy
- 1984 - M.D., University of Rome "La Sapienza", Rome, Italy
- 1984-1987 - Residency in Allergy and Immunology, University of Rome "La Sapienza," Italy
- 1987-1991 - Ph.D. (Immunology), University of Rome, Italy

Other Training:

- 1986 - Authorised User for Radioactive Compounds, Radiation safety branch, National Institute of Health (NIH), Bethesda, Maryland, USA.
- 1988 - Molecular Biology course "Special topics in recombinant DNA technology", Biotrac, Foundation for Advanced Education in the Science, NIH, Bethesda, Maryland, USA.
- 1989 - Biochemistry's course of "Separation techniques", Biotrac, Foundation for Advanced Education in the Science, NIH, Bethesda, Maryland, USA.
- 1993 - Responsible Supervisor for Radioactive compounds, National Safety Branch, National Institute of Health (NIH), Bethesda, Maryland, USA.

Brief Chronology of Employment:

- 1982-1986 - Internship, Department of Allergy and Clinical Immunology, Laboratory of Immunology, University of Rome "La Sapienza," Italy
- 1986 - Fellowship, Italian Cancer Society, Laboratory of Tumor Cell Biology (LTCB), National Cancer Institute (NCI), NIH, Bethesda, Maryland, USA
- 1986-1990 - Visiting Fellow, LTCB, NCI, NIH, Bethesda, Maryland, USA
- 1990-1993 - Visiting Associate, LTCB, NCI, NIH, Bethesda, Maryland, USA
- 1993-1994 - Visiting Scientist, LTCB, NCI, NIH, Bethesda, Maryland, USA
- 1994-1995 - Visiting Scientist (Tenure Track), Head of the Vascular Biology and AIDS-associated Malignancies Unit, LTCB, NCI, NIH, Bethesda, Maryland, USA
- 1996-1999 - Director of Research, Laboratory of Virology, Istituto Superiore di Sanità, Rome, Italy
- 2000-2004 - Director, Retrovirus Division, Laboratory of Virology, Istituto Superiore di Sanità, Rome, Italy
- 2004 - Director, AIDS Division, Department of Infectious, Parasitic and Immune-mediated Diseases, Istituto Superiore di Sanità, Rome, Italy.
- 2005 - Director, National AIDS Center, Istituto Superiore di Sanità, Rome, Italy.

Program Coordinator:

- National AIDS Program, Ministry of Health, Italy.
- AIDS Vaccine Integrated Project (AVIP), FP6, European Commission
- "Very Innovative AIDS Vaccine" (VIAV) (Specific Targeted Research Project), FP6, European Commission.
- Concerted Action on "The use of HIV protease inhibitors in AIDS-associated Kaposi's sarcoma", National AIDS Program, Ministry of Health, Italy.
- Concerted Action on HIV/AIDS vaccine development (ICAV), National AIDS Program, Ministry of Health, Italy.
- Italy-USA inter-institute (Istituto Superiore di Sanità and NIH) cooperation on "HIV/AIDS vaccine development".

and

- Principal Investigator, "Joint Program ISS/Chiron for the development of a combined vaccine against HIV/AIDS". Chiron Corporation, Emerville, California, USA (2002-2005).
- Principal Investigator, Master Clinical Study Agreement for the use of the HIV protease inhibitor Indinavir in the treatment of tumors. Merck & Co., New Jersey, USA.
- Principal Investigator, Mucosal Vaccines for Poverty Related Diseases (MUVAPRED) Integrated Project, FP6, European Commission.

Cooperative Research and Development Agreement with Industries:

Principal Investigator, "Therapy of AIDS-associated Kaposi's sarcoma and other AIDS-associated malignancies by using phosphorothioate oligonucleotides and other analogues directed against basic fibroblast growth factor, other cytokines and the HIV-1 Tat protein". Lynx Therapeutics, Inc., Hayward, California, USA (1993-1995).

Principal Investigator, "Joint Program ISS/Chiron for the development of a combined vaccine against HIV/AIDS". Chiron Corporation, Emerville, California, USA (2002-2005).

Principal Investigator, Master Clinical Study Agreement for the use of the HIV protease inhibitor Indinavir in the treatment of tumors. Merck & Co., New Jersey, USA

Committees and Societies:

- VII International AIDS Conference Program Committee
- International Symposium on Cytokines and HIV, Scientific Committee
- European Conference on Experimental AIDS Research (ECEAR), Scientific Committee and Organizational Committee
- National AIDS Program, Scientific Committee, Ministry of Health, Italy
- AIDS-associated Malignancies Working Group (AMWG) Committee, NCI, NIH, USA
- Italian Association of Immunopharmacology, Scientific Committee
- National Committee for the "Challenge against AIDS and other infectious diseases", Ministry of Health, Italy
- Committee for patent activity of the Istituto Superiore di Sanità, Ministry of Health, Italy
- Scientific Committee, Concerted Action for AIDS Epidemiology, Ministry of Health, Italy

- Organizing Committee, International Conference on Human Herpesvirus-6, -7 and -8
- Italian expert for the European Agency for the Evaluation of Medicinal Products (EMEA)
- Responsible for the Scientific Committee "Italy-USA for the development of vaccines against HIV/AIDS"
- WHO-UNAIDS Vaccine Advisory Committee
- Member of the European Molecular Biology Organization (EMBO)
- American Association of Immunologists (AAI)
- European Steering Committee for the development of a vaccine against HIV/AIDS
- UNESCO delegate for Italy, Vice-President of the Natural Sciences Committee
- United Nations General Assembly for HIV/AIDS (New York , 25-27 June 2001), member of the delegation representing Italy
- Permanent Observatory, "Marisa Bellisario Foundation", for the analysis and the commentary of parliamentary initiatives in public health and scientific research
- National Committee for AIDS, Ministry of Health, Italy
- Scientific Committee, Project "Patologia, Clinica e Terapia dell'AIDS", Istituto Superiore di Sanità.
- Workgroup on Infrastructures and on excellent European networks in the field of biosafety and biotechnology instituted by the National Committee for Biosafety and Biotechnology, Presidenza del Consiglio dei Ministri
- Expert for the European Commission for the assessment of the "Expression of Interests", June 12 2002.
- Conference Organization, XIV International AIDS Conference, Barcelona 7-12 July, 2002
- External examiner in medical sciences for a candidate at the Stellenbosh University, South Africa, 2002
- Member of the board of examiners at the Jawaharlal Nehru Centre for Advanced Scientific Research, for the year 2003.
- Member of the WHO-UNAIDS HIV Vaccine Advisory Committee (VAC), 2004.
- Member of Teaching Scientific Committee of the International PhD courses, German Research Center For Biotechnology (GBF), Germany.
- Member of Guarantee Committee, Consiglio Nazionale delle Ricerche (CNR), Rome, 2005.

Honors and Other Special Scientific Recognition:

- | | | |
|------|---|---|
| 1984 | - | Summa cum laude |
| 1987 | - | Summa cum laude |
| 1990 | - | "Italian Society for AIDS Research" award for the most significant publication in the field of AIDS research for 1989, "AIDS-Kaposi's sarcoma-derived cells express cytokines with autocrine and paracrine growth effects." <u>Science</u> 243: 223-226, 1989 |
| 1991 | - | Summa cum laude |
| 1991 | - | Proposed for Tenure and Head of the Unit of Vascular Biology and AIDS-associated Malignancies by Site Visit Review Board, NCI, NIH, USA |
| 1992 | - | Award from the NIH for contribution to technology transfer from the Laboratory of Tumor Cell Biology to the private sector |
| 1993 | - | Award from the NIH for contribution to technology transfer from the to the Laboratory of Tumor Cell Biology to the private sector |
| 1994 | - | Award from the NIH for contribution to technology transfer from the Laboratory of Tumor Cell Biology to the private sector |
| 1994 | - | Grandfathered into Tenure Track Program, NIH, USA |
| 1998 | - | Scientific award on "vaccinal strategies against AIDS: The Italian experience", conferred by Rome Major Francesco Rutelli and by the Assessor of Cultural Policies Gianni Borgna at Sala dell'Ercole of Musei Capitolini in Campidoglio. |

- 1998 - Award for special professional merits from the Cultural Association “Nuova Immagine Latina” at Palazzo della Cultura, Latina
- 1999 - International Award “San Valentino d’Oro” conferred by the Comitato per la “Premiazione di un messaggio d’Amore for the whole professional activity against AIDS”.
- 1999 - International Award “Premio Marisa Bellisario” conferred by Foundation Marisa Bellisario for professional activities.
- 1999 - International Award “Inner Weel” for professional merits.
- 2000 - “Fiore di Roccia” Award for scientific work given by the Manna Cultural Association, held in the Library Room at CNEL.
- 2000 - Honor (Ufficiale), conferred for scientific achievements by the President of the Italian Republic Mr A. Ciampi, 2000
- 2000 - “Eleonora Benvenuti Turziani” Award for the year 2000, Perugia, for scientific and professional merits.
- 2000 - “Universum” International Award for the year 2000, Potenza, for scientific and professional merits.
- 2000 - “Woman of the year 1999” Award conferred by the magazine “Grazia” (Mondadori Ed.) for scientific and professional merits.
- 2000 - Honorary Member of Medical Women’s International Association (M.W.I.A).
- 2001 - Honor (Cavaliere dell’Ordine al Merito della Repubblica Italiana) conferred by the President of the Italian Republic Mr. A. Ciampi, 2001.
- 2001 - “Domenico Marotta” Award for year 2000, conferred from professional merits by the National Academy of Sciences (also known as “National Academy of XL”) at the Royal Museum of Mineralogy, Naples.
- 2001 - “Graziella Fumagalli” Award for year 2001, conferred from professional merits by the Confartigianato Donna Impresa, Padova.
- 2002 - “Santa Caterina” Award for year 2002, conferred from professional merits by “S. Caterina d’Oro” and “Cateriniani nel Mondo”, Siena.
- 2002 - “Graziella Fumagalli” Award for year 2002, conferred from professional merits by the Confartigianato Donna Impresa, Padova.
- 2002 - “Altipiani d’Arcinazzo” Award for year 2002, conferred from scientific and professional merits.
- 2002 - “R.O.S.A.” Award for the year 2002 conferred from professional merits by the Canova Club.
- 2003 - “Minerva” Award for the year 2003 conferred for scientific and professional merits.
- 2003 - “Italiani nel Mondo” Award for year 2003 (III Edition) conferred for professional merits by the Ministero per gli Italiani nel Mondo (Marzio Tremaglia Foundation), supported by President of the Italian Republic.
- 2004 - Honor (Ufficiale) conferred by the President of the Italian Republic Mr. A. Ciampi, 2004.
- 2004 - “Ordres des femmes de la jarretiere” award for the year 2004 for scientific and professional merits.
- 2004 - International Award “Paul Harris Fellow” conferred by the Rotary Foundation for professional activities.
- 2004 - “Vittorio Bachelet” award conferred for her Vaccine against AIDS.
- 2004 - “Gentile da Fabriano” national award conferred for scientific and professional merits.
- 2004 - “Stella” national award for the year 2004, conferred by the Associazione Italiana Ospedalità Privata (A.I.O.P.) for professional activities.
- 2005 - “Donna Emerita” national award conferred by the Federazione Italiana “Donne, Arti, Professioni ed Affari”, Padova, for scientific and professional merits.

- 2005 - "Premio Internazionale alle Libertà", conferred by the Associazione di Cultura Liberale "Società Libera", Milano, for scientific and professional merits.
- 2005 - "Eminent Scientist of the Year 2005" International Award for Europe, conferred by the International Research Promotion Council – World Scientist Forum International Award –Science and Medicine, for scientific and professional merits.

Teaching:

- Georgetown University, Washington, USA; Tulane University School of Medicine, New Orleans, USA; NIH, Bethesda, Maryland, USA; Columbia University, New York, USA.
- External Examiner: MSc in Medical Sciences (Medical Virology), Candidate Mr. TS Scriba (12721255-1997), University Office Tygerberg Campus, Africa, 2002.
- Member of Teaching Scientific Committee of the International PhD courses, University of Ferrara, Stockholm and German Research Center For Biotechnology (Germany).
- Courses to Medical Doctors on AIDS pathogenesis, AIDS-associated tumors, angiogenesis, HIV/AIDS vaccine development at the University of Ferrara, Ferrara, Italy.
- Appointed Professor, Medical School, University of Ferrara, Ferrara, Italy (1999/2000, 2000/2001, 20001/2002, 2002/2003, 2003/2004, 2004/2005, 2005/2006).
- Advisory of the Teaching Scientific Committee of the PhD courses in Experimental Oncology, University of Ferrara, Ferrara, Italy.
- Member of the Microbiology and Virology Post-Graduate School Committee and University teacher for the integrative course "Innovative vaccines", Microbiology and Virology School, Faculty of Medicine, University of Brescia, Italy.
- University teacher on "Novelty in oncohaematology" (November 29-30, 2002, Legnano), Legnano Hospital, Italy.
- Member of Teaching Scientific Committee of the International PhD courses in Medical Immunemicrobiology, University of Rome "Tor Vergata", Rome, Italy.
- Warrant (designated by "Centro Nazionale Ricerche", year 2005) for the disciplinary aggregation of expertise, with the task of proposing the nominees of the members of the boards of examiners recruiting personnel (investigators and technicians) and for personnel promotions.

Patents:

- Ensoli, B. and Gallo, R.C.: Method for treating Kaposi's sarcoma with antisense oligonucleotides, (U.S. and European Patent, No. 5990088, November 23, 1999).
- Ensoli B.: HIV-1 Tat, or derivatives thereof, alone or in combination, for prophylactic and therapeutic vaccination. (Italian patent, priority date December 1, 1997 N. 1297090; PCT

November 30, 1998, No. PCT/EP98/07721, Publication No. WO99/27958; European Patent Application No. 98966601.1, priority date November 30, 1998).

- Ensoli B.: Employment of human immunodeficiency virus (HIV) protease inhibitors (HIV-PI) for utilizing them as drugs or realizing new anti-angiogenic, anti-tumor, anti-edemic, anti-inflammatory drugs, for the treatment of Kaposi's sarcoma, tumors and angioproliferative, inflammatory and autoimmune diseases in HIV infected or non infected subjects (European Patent application, No. RM2001 A000210, priority date April 18, 2001; PCT April 18, 2002, No. PCT/EP02/04303, Publication No. WO02/087583).
- Ensoli B.: Use of biologically active HIV-1 Tat, fragments or derivatives thereof, to target and/or to activate antigen-presenting cells, and/or to deliver cargo molecules for preventive or therapeutic vaccination and/or to treat infectious diseases, inflammatory and angiogenic diseases, and tumors. (European Patent application, No. 01118114.6, priority date July 26, 2001, PCT July 26, 2002, No. PCT/EP02/08377, Publication No. WO03/009867).
- Ensoli B., Gavioli R., Caputo A.: Vaccines (United Kingdom Patent application, No. 0323840.9, priority date October 10, 2003; PCT October 10, 2004, No. PCT/EP2004/11950).
- Ensoli B., Caputo A., Laus M., Tondelli L., Sparnacci K. Nanoparticles for delivery of a pharmacologically active agent (United Kingdom Patent application, No. 0325625.2, priority date November 3, 2003; PCT November 3, 2004, No. PCT/EP2004/012420).
- Ensoli B., Caputo A., Gavioli R., Tondelli L., Laus M., Sparnacci K. Use of microparticles for antigen delivery (United Kingdom Patent application, No. 0325624.5, priority date November 3, 2003; PCT November 3, 2004, No. PCT/EP2004/012421).
- Ensoli B. Novel Tat complexes, and vaccines comprising them (United Kingdom Patent application, No. 0405480.5, priority date March 11, 2004; PCT March 11, 2005, No. PCT/EP2005/003043).
- Ensoli B., Marconi P., Caputo A. Recombinant Herpes Simplex Virus And Uses Therefor (United Kingdom Patent application, No. 0406389.7, priority date March 22, 2004; PCT March 22, 2005; No. PCT/EP2005/003635).
- Ensoli B., Peng B., Voltan R., Robert-Guroff M. Improved replication-competent adenoviral vectors (US Patent Application, No. 60/629,722 - priority date November 18, 2004)

Editorial Board Member:

Lancet Oncology

Reviewer for Journals:

AIDS

AIDS Research and Human Retroviruses

American Journal of Pathology

Archives of Oral Biology

Blood
 Cancer
 Cancer Research
 Cell Death and Differentiation
 Clinical Cancer Research
 EMBO Journal
 European Journal of Immunology
 Expert Opinion on Investigational Drugs
 FEBS Letters
 Gene Therapy
 Human Gene Therapy
 International Journal of Cancer
 Journal of Acquired Immunodeficiency Syndrome
 Journal of Clinical Investigation
 Journal of General Virology
 Journal of Immunology
 Journal of Infectious Diseases
 Journal of Neuroscience
 Journal of Virology
 Laboratory Investigation
 Microvascular Research
 Nature
 Nature Medicine
 New England Journal of Medicine
 Oncogene
 Proceedings of the National Academy of Sciences, USA
 The American Journal of Pathology
 Trends in Biotechnology
 Vaccine
 Virology

Reviewer of Grants for:

- Louisiana Education Quality Support Fund, Research and Development Program NIH Grants, USA
- NIH Grants, Ohio State University Comprehensive Cancer, The Ohio State University, USA
- Center National Health Research and Development Program, Canada
- Wellcome Trust registered Charity, London, UK
- Extramural AIDS grants, Ministry of Health, Italy
- European Molecular Organization (EMBO), Germany

Experiences related to HIV/AIDS

Study of virus-host interaction with particular regard to the effects of viral products. First demonstration that the Tat protein of HIV-1 is released by acutely infected cells and exerts key activities on the virus and on endothelial cells. Role of the HIV-1 Tat protein, cytokines and HHV-8 in the pathogenesis of AIDS-associated Kaposi's Sarcoma. Biology of angiogenic growth factors. Gene therapy approaches for the inhibition of HIV-1 replication *in vitro* and AIDS-associated tumor development *in vivo*. Role of HIV-1 protease inhibitors as anti-angiogenic factors in promoting regression of AIDS-Kaposi's sarcoma. Development of anti-HIV vaccines based on Tat protein or Tat-DNA which were found capable of

inhibiting virus replication and AIDS development in monkeys. Studies on the role of Tat as adjuvant: uptake by dendritic cells, induction of their maturation and promotion of their capacity to present antigens and to elicit T cell responses to other antigens. Studies on the humoral and cellular immune response to virus antigens during the natural course of infection and correlation with disease stages. Standardization of tests for the evaluation of humoral and cellular immune response to viral proteins and virological parameters for monitoring immunogenicity and efficacy of vaccine candidates in clinical trials. New immunization strategies to induce both systemic and mucosal immunity. Studies of vaccination strategies based on the combination of Tat with other viral regulatory and structural proteins. Cooperation with the industry to the development of novel therapeutic strategies. Implementation of production and purification protocols for large scale GLP and GMP production of candidate antigens. Organization and conduction of phase I preventive and therapeutic clinical trials for the Tat-based vaccine against HIV/AIDS in Italy; organization of phase II clinical trials in Africa (Uganda, South Africa and Swaziland). Coordination of the Italian “Concerted Action on development of a vaccine against AIDS” (ICAV), established under the Italian National AIDS Research Project with the aim to develop new preventive and therapeutic vaccine strategies to curb the HIV pandemic, consisting of a network of highly-qualified Italian Research Groups with different types of expertise required to develop a HIV translational research program. Coordination of the Joint Program ISS/Chiron for the development of a vaccine against AIDS based on the combination of Tat and Env and/or Gag. Coordination of the “AIDS Vaccine Integrated Project” (AVIP), awarded by the European Community within the FP6 Integrated Project on Poverty Diseases, involving a network of 15 European and African research groups, to the aim of developing preventive and therapeutic vaccines against HIV/AIDS based on the combination of structural and regulatory proteins.

Field Experiences related to HIV/AIDS

Role of Tat protein of HIV-1 and the Human Herpes virus 8 (HHV-8) in the pathogenesis of Kaposi’s Sarcoma, an angioproliferative disease which is present at high frequencies in Africa. Studies on transmission of HHV-8 infection in Egypt, Cameroon, Uganda and Papua New Guinea, demonstrating non sexual transmission of HHV8 among adults and absence of vertical transmission (mother-to-child) in children. Membership of an International Collaborative Group and participation in studies on variability and evaluation of Kaposi’s sarcoma-associated herpesvirus in Europe and Africa. Immunological and virological studies in the field of HIV infection in African countries (South Africa, Uganda, Swaziland, and Ivory Coast), preliminary to phase II/III clinical trials with a vaccine against HIV/AIDS based on the biologically-active Tat protein, developed at ISS. Molecular epidemiological studies in Uganda and South Africa for determination of locally circulating HIV subtypes. Studies on variability of Tat protein in Uganda and South Africa in field isolates from patients infected with different HIV subtypes. Standardization of immunological and virological tests in genetically and environmentally different human populations in Africa (Uganda, South Africa, Swaziland) where phase II/III trials with the Tat-based vaccine are planned. Epidemiological feasibility studies to identify potential cohorts for phase II/III clinical trials. Studies in Uganda demonstrating the presence of an immune activation in HIV-infected African patients environmentally driven and associated with up-regulation of the HIV co-receptor CCR5. Establishment of collaborations with African countries for the development of clinical trials with the Tat-based vaccine.

BIBLIOGRAFY

1. Paganelli R., Capobianchi M.R., Le Moli S., Facchini J., Matricardi P.M., Bonomo G., **Ensoli B.**, Aiuti F., and Dianzani F. Gamma-interferon production *in vitro*: A marker for immunoregulatory defects in immunodeficiencies. In Griscelli G. and Vossen J. (Eds.): Progress in Immunodeficiency Research and Therapy I. Elsevier, 1984, pp. 267-269.
2. Aiuti F., **Ensoli B.**, Scarpati B., Carbonari M., Scano G., Papetti C., Sirianni M.C., and Rossi P. Nuovi aspetti eziologici, epidemiologici ed immunologici della sindrome da immunodeficienza acquisita (AIDS) e delle sindromi ad essa correlate in Italia. Med. Riv. EMI (Italian) 4: 383-390, 1984.
3. Aiuti F., D'Amelio R., Paganelli R., Cherchi M., **Ensoli B.**, and Scano G. Intestinal pathology in immunodeficiencies and autoimmune diseases. In Vierucci, A. (Ed.): Immunity and Infections in the Intestinal Tract and Liver in Children. Florence, Masson Italia, 1984, pp. 5-59.
4. Paganelli R., Le Moli S., **Ensoli B.**, Seminara R., Cabello A., Gaetano G., Cherchi M., Venuta S., and Aiuti F. Production of interleukin-2 and receptor expression in primary and acquired immunodeficiencies. In 8th Conference of the Italian Society of Immunology and Immunopathology (Italian). Milan, O.I.C. Medical Press, 1984, pp. 73-77.
5. Aiuti F., Papetti C., **Ensoli B.**, Cabello A., and Paganelli R. Immunodeficiency and allergy. In Proceedings of the XXXIV National Conference progress in tradition (Italian). Bologna, 1984, pp. 505-509.
6. Aiuti F., Paganelli R., **Ensoli B.**, Cabello A., Cherchi M., Venuta S., Capobianchi M.R., and Dianzani F. Abnormalities of T cell subsets and lymphokines (IL-2 and gamma IFN) in immunodeficiencies. In Aiuti, F., Rosen, F., and Cooper, M.D. (Eds.): Recent Advances in Primary and Acquired Immunodeficiencies. New York, Raven Press, 1984, pp. 155-164.
7. Crescenzi M., Carbonari M., Bonomo R., **Ensoli B.**, Soddu S., and Cafaro A. Clinical use with gamma globulin IV (endobulin) Quaderni di Medicina e Chirurgia (Italian) 8: 151-153, 1984.
8. Fiorilli M., Quinti I., Russi G., Seminara R., **Ensoli B.**, and Aiuti F. Thymopentin treatment for selective IgA deficiency. Karger's Surv. Immunol. Res. 4 (Suppl. 1): 129-134, 1985.
9. **Ensoli B.**, Cabello A., Cherchi M., Venuta S., Capobianchi M.R., and Paganelli R.: Produzione di interleuchina-2, gamma-interferon ed espressione del recettore Tac in sei casi di sindrome linfadenopatica (LAS). In Clot and Hematologic Malignancies, Vol. 2, 1985, pp. 108-112.
10. Aiuti F., Capobianchi M.R., Paganelli R., **Ensoli B.**, Cabello A., Sirianni M.C., Facchini J., and Dianzani F. Further studies on interferon-gamma production in patients with primary immunodeficiency. In The Interferon System. New York, Raven Press, 1985, pp. 397-403.
11. Fiorilli F., Carbonari M., Crescenzi M., **Ensoli B.**, Gaetano C., and Russo G. *In vitro* functional analysis of T lymphocytic subpopulations. In Proceeding of the 17th Conference on Allergology and Immunology. Florence, Masson Italia, 1985, pp. 107-111.
12. Pandolfi F., De Rossi G., Mariani G., Carbonari M., **Ensoli B.**, Napolitano M., Lopez M., Mandelli F., and Aiuti F. Impairment of cellular immunity and OKT4 lymphocytes in symptom-

- free hemophiliacs with antibodies to human T leukemia virus III (HTLV III). Diagnostic Immunol. 3: 155-159, 1985.
13. Aiuti F., Scarpati B., Scano G., Carbonari M., Mannella E., Gaetano C., Mezzaroma I., and **Ensoli B.** Further studies on HTLV-III infection in Italy. In ADS and Blood transfusion, proceedings of the Int. Symposium, Turin, June 13-15, 1985, pp. 9-13.
 14. Biagiotti R., Alessi A., Mazzetti M., Almerigogna F., Giudizi M.G., Del Prete F., Longo G., Morfini M., Romagnani S., **Ensoli B.**, and Napolitano M. Anomalie della produzione *in vitro* di immunoglobuline da parte dei linfociti di sangue periferico di pazienti emofilici. Rapporti con le alterazioni delle popolazioni linfocitarie T e con la presenza nel siero di anticorpi anti-HTLV III. Immunologia Clinica e Sperimentale IV: 101-107, 1985.
 15. Ferrante E., Lorenzini F., Bonamico N., **Ensoli B.**, Rossi F., Manuelli A. and Signorotti A. Sindrome da immunodeficienza acquisita (AIDS) in una bambina di 11 mesi, figlia di tossicodipendenti. In XLIV Congresso Nazionale della Società Italiana di Pediatria (Messina), 28-31 ottobre, 1985.
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